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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,843	02/07/2001	Tamas Lukacovich	2000-1561A	2951

7590 03/27/2003

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,843	Applicant(s) LUKACSOVICH ET AL.	
	Examiner Ram R. Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-15 are pending.
2. Applicant's election of the invention of group I in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 16-19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.
4. Claims 1-15 are under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 9 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 is directed to a vector derived from the vector pCasperhs, which has heat shock promoter directed Gal4 activator domain-large T antigen fusion gene within the polycloning site of the pCasperhs.

In analyzing whether the written description requirement is met for an invention, it is first determined whether the invention has been described by its complete structure. In the instant case, the complete structure of the vector pCasperhs has not been described. It is noted that while the claim discloses as to

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how pCasperhs is modified to make the claimed vector, the structure of the starting material is not disclosed.

Next, then, it is determined whether the invention has been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, again the specification does not disclose the characteristics of the starting vector.

Therefore, claimed invention does not meet the written description requirement.

7. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 9 is directed to a vector derived from the vector pCasperhs, which has heat shock promoter directed Gal4 activator domain-large T antigen fusion gene within the polycloning site of the pCasperhs.

The specification does not teach the structure of the vector pCasperhs, what are its elements and how to make the vector. It is noted that this is the base vector for making the vector of claim 9. Neither the art of record nor the specification teaches how to make the pCasperhs vector. Pirrotta (1988) described the basic structure of the vector pCaSper vector that carries a visible marker for Drosophila, however, Pirrotta does not teach how to modify this vector to make pCasperhs. An artisan of skill would have not known what sequence elements to introduce in the base vector of Pirrotta to make the pCasperhs and would have required extensive experimentation to determine what to include in the vector. In view of the lack of the written description of the base vector as discussed in paragraph 6, an artisan of skill would not have known what are the parts of the vector pCasperhs and therefore would not be able to introduce the elements of the claimed vector.

The application discloses a vector that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this

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biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 2, 4, 8, 9, 10, 11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 9 and 11 are indefinite because it recites the phrase "the recombinant plasmid is derived from". The metes and bounds of the claimed invention are indefinite because it is unclear as to what parts of the base vector are present in the product.

Claims 8 and 15 are indefinite because the antecedent basis for the term "its promoter" in line 2 of claim 8 and line 3 of claim 15 is not clear. It is noted that claim 1 or claim 10 do not recite a promoter and these claims do not recite that the drug resistance gene in claims 1 and 10 comprises a promoter.

Claim 10 is indefinite because it is unclear as to which drug is the step b reciting and whether it is related to the drug resistance gene of the vector.

Claim 4 is vague and indefinite because it is unclear as to whether "which" in line 1 refers to the vector or claim 3.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-3, 5-8 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sands et al (US 6,136,566, 10-24-00, effective filing date 10-4-1996) in view of Thummel et al (Gene 74:445-456, 1988) and Pirrotta et al (Biotechnology Vectors a survey of molecular cloning vectors and their uses, ed. RL Rodriguez et al. Vol 1, 1988, pages 437-456, Butterworths Press, Boston) and Gustafson K, Boulianne GL (Genome 1996 39(1):174-82).

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At the time of the invention, Sands et al taught 3' gene trap cassettes comprising splice acceptor, beta-gal (marker gene), a promoter driving expression of an exon with a unpaired splice donor site at the 3' end. The exon encodes a selectable marker (see figure 2 and columns 3-8). The exon may be any other gene. When the vector is integrated into the intron of a gene into the genome of a cell, beta gal is expressed under the control of the promoter of the gene. The unpaired splice donor site of the exon when splices with the acceptor site of the gene the selectable marker is expressed. The art does not teach a vector that comprises a gene for detectable phenotype in *Drosophila melanogaster* in addition to the marker and selectable marker genes.

Thummel et al and Pirrotta et al teach vectors for *Drosophila* P-element mediated transformation and tissue culture transfection, of which pCasper is one of the vectors. The vector contains 5' and 3' P element transposons, sequence encoding white gene, and LacZ gene or actin gene, AUG codon (see figure 1 in Thummel et al or figure 22-1 to 22-3 in Pirrotta et al). The arts discuss the use of these vectors for inactivating a gene or its vicinity and produce detectable phenotype (see section 22.13 in Pirrotta et al). The art also teaches modification of the vector by substituting the P promoter with hsp70 promoter and modifications that would allow mass treatment of large number of eggs to that to rescue a desired phenotype.

At the time of the invention it would have been obvious to an artisan of ordinary skill to modify the vector of Sands et al by cloning white gene sequences in the exon that would allow a screening of phenotype in *Drosophila* or clone the vector of Sands in the pCasper vector with a reasonable expectation of success since the methods of cloning genes and modifying vectors was routine in the art as taught in the arts of Sands et al, Thummel et al or Pirrotta. An artisan would have cloned the white gene in the vector of Sand because this would have allowed trapping of genes in *Drosophila*. Additionally, an artisan would have been motivated to modify pCasper vector because it would have allowed the use of P element transposons that would result in trapping of multiple gene due to the transposition property of P element.

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An artisan of skill would have been motivated to modify the vector of Sands by substituting the reporter gene with Gal4-UAS system with a reasonable expectation of success because the use of GAL4-UAS system was routine in the art of Drosophila gene trap techniques at the time of the invention. An artisan of skill would have been motivated to use the system because this would have allowed a two part detection system, first mobilization of Gal4 in the entire genome of Drosophila and then after crossing over the GAL4 flies with LACZ flies that allow expression under UAS transcriptional control as taught by Gustafson et al. Regarding the use of luciferase reporter gene in claim 13, it is noted that any reporter gene could be used in place of LACZ, for example, luciferase or GFP etc. and such modifications or substitutions of the reporter genes were routine in the art (see Sands et al).

12. The vector of claim 4 is free of the art of record.

13. Claim 4 is objected to because it is dependent on rejected claims. If the claim was presented in an independent form with all the limitations of the claims it is dependent on, the claim will be allowable.

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this

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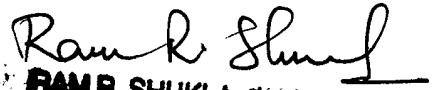
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application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

Ram R. Shukla, Ph.D.

Primary Examiner

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RAM R. SHUKLA, PH.D.
PATENT EXAMINER